

DOCKET NO.: PHOE-0188

PATENT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**In Re Application of:**

**Mike A. Clark**

**Application No.: 10/757,843**

**Filing Date: January 15, 2004**

**For: MODIFIED ARGININE DEIMINASE**

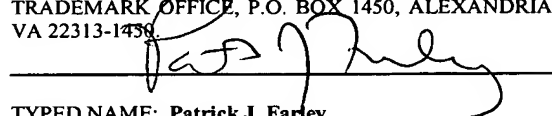
**Confirmation No.:**

**Group Art Unit: Not Yet Assigned**

**Examiner: Not Yet Assigned**

DATE OF DEPOSIT: AUG. 16, 2004

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE UNITED STATES PATENT AND TRADEMARK OFFICE, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

  
TYPED NAME: Patrick J. Farley  
REGISTRATION NO.: 42,524

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

**INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

- ☒ In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of

the above identified application as set forth in § 1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

- ☐ In accordance with § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Certification in Accordance with § 1.97(e) is attached; or

☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.

- ☐ In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:

☐ Certification in Accordance with § 1.97(e) is attached;

or

☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.

- ☐ In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of \$180.00 as set forth in § 1.17(p).

- ☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.
- ☒ Copies of references listed on the attached Form PTO-1449 are enclosed herewith
- ☐ Copies of references listed on the attached Form PTO 1449 are not required to be submitted pursuant to the June 30, 2003 recent revisions to 37 CFR § 1.98(a)(2)(i).

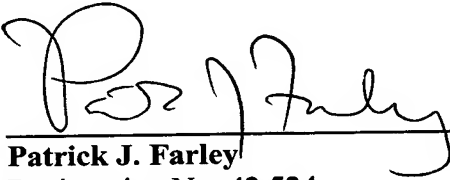
## EXCEPT THAT:

- ☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☒ In accordance with § 1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application:
- ☒ Copies of references **1 thru 46 and 52 thru 71** listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior Application No. **09/723,546** filed **November 28, 2000**.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

Enclosed is a copy of EPO Partial European Search Report dated **July 19, 2004**, which indicates the references to be relevant.

Date: *Aug. 16, 2004*

  
**Patrick J. Farley**  
Registration No. **42,524**

**WOODCOCK WASHBURN LLP**  
One Liberty Place - 46th Floor  
Philadelphia, PA 19103  
Telephone: (215) 568-3100  
Facsimile: (215) 568-3439



<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office		Docket No. <b>PHOE-0188</b>	Application No. <b>10/757,843</b>
		Applicant <b>Mike A. Clark</b>	
		Filing Date <b>January 15, 2004</b>	Group <b>Not Yet Assigned</b>
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	1	Abuchowski, A. et al., "Effect of Covalent Attachment of Polyethylene Glycol on Immunogenicity and Circulating Life of Bovine Liver Catalase", <i>J. Biol. Chem.</i> , <b>1977</b> , 252(11), 3582-3586	
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	7	Jones, J.B., "The Effect of Arginine Deiminase on Murine Leukemic Lymphoblasts", <i>Ph.D. Dissertation, The University of Oklahoma</i> , <b>1981</b> , 1-165	
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	10	Kidd, J.G. "Aspariginase and Cancer-Yesterday and Today", <i>Cancer Res.</i> , <b>1970</b> , 33, 1-14	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	

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	<b>11</b>	Kondo, K. et al., "Cloning and Sequence Analysis of the Arginine Deiminase Gene from Mycoplasma Arginini", <i>Mol. Gen. Genet.</i> , <b>1990</b> , 221, 81-86
	<b>12</b>	Misawa, S. et al., "High-Level Expression of Mycoplasma Arginine Deiminase in Escherichia Coli and Its Efficient Renaturation as an Anti-Tumor Enzyme", <i>J. Biotechnology</i> , <b>1994</b> , 36, 145-155
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	<b>16</b>	Oginsky, "[92] Isolation and Determination of Arginine and Citrulline", <i>Meth. Enzymol.</i> , <b>1957</b> , 3, 639-642
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	<b>21</b>	Stocks, S.J. et al., "A Fluorometric Assay of the Degree of Modification of Protein Primary Amines with Polyethylene Glycol", <i>Analyt. Biochem.</i> , <b>1986</b> , 154, 232-234
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	<b>23</b>	Sugimura, K. et al., "High Sensitivity of Human Melanoma Cell Lines to the Growth Inhibitory Activity of Mycoplasmal Arginine Deiminase in Vitro", <i>Melanoma Res.</i> , <b>1992</b> , 2, 191-196
	<b>24</b>	Sugimura, K. et al., "Identification and Purification of Arginine Deiminase that Originated from Mycoplasma Arginini", <i>Infect Immun.</i> , <b>1990</b> , 58*8, 2510-2515
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	<b>31</b>	van Wagendonk, et al., "Nitrogen metabolism in protozoa", <i>Comparative Biochemistry of Nitrogen Metabolism (J.W. Campbell ed.)</i> , 1970, 1-56
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	<b>37</b>	Craig, S. et al., "Single amino acid mutations block a late step in the folding of B-Lactamase from <i>Staphylococcus aureus</i> ", <i>J. Mol. Biol.</i> , 1985, 185, 681-687
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	<b>40</b>	Takaku, H. et al., "Anti-tumor Activity of Arginine Deiminase from <i>Mycoplasma arginini</i> and Its Growth-inhibitory Mechanism," <i>Jpn. J. Cancer Res.</i> , September 1995, 86(9), 840-846
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	<b>41</b>	Fraser, C. et al., "Borrelia burgdorferi (section 69 of 70) of the complete genome", <b>12/16/1997</b> , Database Accession no. AE001183, XP 002211866
	<b>42</b>	Knodler, Leigh A. et al., "Cloning and Expression of a Prokaryotic Enzyme, Arginine Deiminase., from a Primitive Eukaryote <i>Giardia intestinalis</i> ", <i>Journal of Biological Chemistry</i> , <b>02/20/1998</b> , 273(8), 4470-4477, XP-002211868
	<b>43</b>	Takaku, et al., <i>Jpn J. Cancer Res.</i> , <b>1993</b> , 84, 1195-200
	<b>44</b>	Poyart, et al., <i>International Journal of Systematic and Evolutionary Microbiology</i> , <b>2002</b> , 52, 1247-1255
	<b>45</b>	Tettelin, et al., <i>Science</i> , <b>2001</b> , 293, 498-506
	<b>46</b>	Degnan, et al., <i>Infection and Immunity</i> , <b>1998</b> , 66(7), 3050-3058
	<b>47</b>	Clark, R., et al., "Long-Acting Growth Hormones Produced by Conjugation with Polyethylene Glycol", <i>journal of Biological Chemistry</i> , <b>1996</b> , 271, 21969-21977, XP-002216386
	<b>48</b>	Gaertner, H.F. et al., "Site-Specific Attachment of Functionalized Poly(Ethylene Glycol) to the Amino Terminus of Proteins", <i>Bioconjugate Chem.</i> , <b>1996</b> , 7, 38-44, XP-000791225
	<b>49</b>	Kita, Y. et al., "Characterization of a Polyethylene Glycol Conjugate of Recombinant Human Interferon- $\gamma$ ", <i>Drug Design and Delivery</i> , <b>1990</b> , 6, 157-167
	<b>50</b>	Rigneault, H. et al., "Extraction of Light from Sources Located Inside Waveguide Grating Structures", <i>Optice Letters</i> , <b>1999</b> , 24(3), 148-150, XP-000803121
	<b>51</b>	Molnar, S. et al., "Pharmacology of a Peg-Conjugated Arginine Deiminase", <i>Faseb Journal</i> , <b>1993</b> , 7, pg A391, XP009002632
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<b>U. S. PATENT DOCUMENTS</b>							
<b>Examiner Initial</b>		<b>Document No.</b>	<b>Date</b>	<b>Name</b>	<b>Class</b>	<b>Subclass</b>	
	52	4,179,337	12/18/79	Davis, et al.	435	181	
	53	4,609,546	09/02/86	Hiratani	424	83	
	54	5,447,722	09/05/95	Lang, et al.	424	280.1	
	55	5,468,478	11/21/95	Saifer, et al.	424	78.27	
	56	5,474,928	12/12/95	Takaku, et al.	435	228	
	57	5,372,942	12/94	McGarrity, et al.	435	227	
	58	5,804,183	08/98	Filpula, et al.	424	94.6	
	59	5,916,793	06/02/99	Filpula, et al.	435	195	
<b>FOREIGN PATENT DOCUMENTS</b>							
<b>Examiner Initial</b>		<b>Document No.</b>	<b>Date</b>	<b>Country</b>	<b>Translation</b>		
					<b>YES</b>	<b>NO</b>	
	60	WO 94/05332	03/17/94	PCT			
	61	WO 96/34015	10/31/96	PCT			
	62	JP 4 121 187	04/22/92	Japan			
	63	EP 0 372 752 A2	06/13/90	EPO			
	64	JP 53490	02/22/90	Japan			
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**U. S. PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Name	Class	Subclass
	65	6,132,713	10/17/00	Fiipula, et al.	424	94.3

**FOREIGN PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Country	Translation	
					YES	NO
	66	EP 0 230 777 A1	08/87	EPO		
	67	EP 0 414 007 A2	02/27/91	EPO		
	68	EP 0 897 011 A2	02/17/99	EPO		
	69	WO 98/33519	08/06/98	PCT		
	70	WO 98/51784	11/19/98	PCT		
	71	JP 3 209 338	09/17/01	Japan		
	72	EP 0 442 724 A2	08/21/91	EPO		

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